Mortara

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REF 9515-174-50-ENG Rev F1

# WAM

WIRELESS ACQUISITION MODULE

## USER MANUAL

Manufactured by Mortara Instrument, Inc., Milwaukee, Wisconsin U.S.A.

CE

***CAUTION:*** *Federal law restricts this device to sale by or on the order of a physician.*

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- Assembly operations, extensions, readjustments, modifications, or repairs are carried out only by persons authorized by Mortara Instrument, Inc.
- The device is used in accordance with the instructions for use.

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## Equipment Identification

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Consumable, disposable or single use products such as, but not limited to, PAPER or ELECTRODES are warranted to be free from defects in workmanship and materials for a period of 90 days from the date of shipment or the date of first use, whichever is sooner.

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a) Freight damage;

b) Parts and/or accessories of the Product/s not obtained from or approved by Mortara;

c) Misapplication, misuse, abuse, and/or failure to follow the Product/s instruction sheets and/or information guides;

d) Accident; a disaster affecting the Product/s;

e) Alterations and/or modifications to the Product/s not authorized by Mortara;

f) Other events outside of Mortara's reasonable control or not arising under normal operating conditions.

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# USER SAFETY INFORMATION

**Warning:** Means there is the possibility of personal injury to you or others.

**Caution:** Means there is the possibility of damage to the device.

**Note:** Provides information to further assist in the use of the device.

## Warning(s)

- This manual gives important information about the use and safety of this device. Deviating from operating procedures, misuse or misapplication of the device, or ignoring specifications and recommendations could result in increased risk of harm to users, patients and bystanders, or damage to the device.
- Device transmits data reflecting a patient's physiological condition to a properly equipped receiving device that when reviewed by a trained physician or clinician can be useful in determining a diagnosis; however, the data should not be used as a sole means for determining a patient's diagnosis.
- Users are expected to be licensed clinical professionals knowledgeable about medical procedures and patient care, and adequately trained in the use of this device. Before attempting to use this device for clinical applications, the operator must read and understand the contents of the user manual and other accompanying documents. Inadequate knowledge or training could result in increased risk of harm to users, patients and bystanders, or damage to the device. Contact Mortara service for additional training options.
- To maintain designed operator and patient safety, peripheral equipment and accessories used that can come in direct patient contact must be in compliance with UL 60601-1, IEC 60601-1, and IEC 60601-2-25. Only use parts and accessories supplied with the device and available through Mortara Instrument, Inc.
- Patient cables intended for use with the device include series resistance (9 Kohm minimum) in each lead for defibrillation protection. Patient cables should be checked for cracks or breakage prior to use.
- Conductive parts of the patient cable, electrodes, and associated connections of type CF applied parts, including the neutral conductor of the patient cable and electrodes, should not come into contact with other conductive parts including earth ground.
- ECG electrodes could cause skin irritation; patients should be examined for signs of irritation or inflammation.
- To avoid the possibility of serious injury or death during patient defibrillation, do not come into contact with device or patient cables. Additionally, proper placement of defibrillator paddles in relation to the electrodes is required to minimize harm to the patient.
- Defibrillation protection is guaranteed only if the original patient cable is used. Any modification of this device may alter defibrillator protection.
- To avoid potential for spread of disease or infection, single-use disposable components (e.g., electrodes) must not be reused. To maintain safety and effectiveness, electrodes must not be used beyond their expiration date.

- This device was designed to use the electrodes specified in this manual. Proper clinical procedure must be employed to prep the electrode sites and to monitor the patient for excessive skin irritation, inflammation, or other adverse reactions. Electrodes are intended for short-term use and should be removed from the patient promptly following testing.

- FCC Warning (Part 15.21): Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the device.

- A possible explosion hazard exists. Do not use the device in the presence of a flammable anesthetic mixture.

- The device has not been designed for use with high-frequency (HF) surgical equipment and does not provide a protective means against hazards to the patient.

- The quality of the signal produced by the device may be adversely affected by the use of other medical equipment, including but not limited to defibrillators and ultrasound machines.

- There is no known safety hazard if other equipment, such as pacemakers or other stimulators, is used simultaneously with the device; however, disturbance to the signal may occur.

- Operations may be affected in the presence of strong electromagnetic sources such as electrosurgery equipment.

- The battery operated device transmits data reflecting a patient's physiological condition to a receiving device. During operation failure, data transmission and LCD information will cease to occur. In mission critical conditions, it is advisable to have a backup device available.

- Use only recommended alkaline battery cells. Use of other cells may present a risk of fire or explosion.

- Low battery warning function is designed for alkaline battery cells only. Use of other cells may result in failure of the low battery warning possibly resulting in a malfunction of the device.

- Do not attempt to clean the device or patient cables by submersing into a liquid, autoclaving, or steam cleaning as this may damage equipment or reduce its usable life. Use of unspecified cleaning/disinfecting agents, failure to follow recommended procedures, or contact with unspecified materials could result in increased risk of harm to users, patients and bystanders, or damage to the device. Do not sterilize the device or patient cables with Ethylene Oxide (EtO) gas. Refer to section 4 for proper cleaning and disinfection instructions.

- The ELI 350 does not automatically switch between the device and a direct patient cable. Clinician must choose the desired cable in the Settings menu before ECG acquisition. Switching between a direct patient cable and the device does not require the device to be re-paired with the ELI 350 unless a different device is to be used. The selected patient cable will display continuously under the Settings menu button.

## Caution(s)

- To prevent possible damage to the device, do not use sharp or hard objects to depress buttons, only use fingertips.
- The device and lead wires should be cleaned between each use. Inspect connections for damage or excessive wear prior to each use. Replace lead wires if damage or excessive wear is noted.
- Do not pull or stretch patient cables as this could result in mechanical and/or electrical failures. Lead wires should be stored after forming them into a loose loop.
- The device will only work with receiving devices that are equipped with the appropriate option.
- No user-serviceable parts are inside. Damaged or suspected inoperative equipment must be immediately removed from use and must be checked/repaired by qualified service personnel prior to continued use.
- This device is not recommended for use in the presence of imaging equipment such as Magnetic Resonance Imaging (MRI) and Computed Tomography (CT) devices, etc.
- The following equipment may cause interference with the RF channel: microwave ovens, diathermy units with LANs (spread spectrum), amateur radios, and government radar.
- When necessary, dispose of the device, its components and accessories (e.g., batteries, cables, electrodes), and/or packing materials in accordance with local regulations.
- AA batteries are known to leak their contents when stored in unused equipment. Remove battery from device when not used for an extended period of time.
- Be careful to insert the connector block into the appropriate input connector by matching the lead wire labels to the device label.
- To prevent possible damage to the device during transport and storage (while in original packaging) the following environmental conditions must be adhered to:

  **Ambient Temperature Range:** -20°C to 65°C (-4°F to 149°F)
  **Relative Humidity Range:** 5% to 95% (non-condensing)
  **Atmosphere Pressure:** 500 hPa to 1060 hPa

- This device is intended to be used in a hospital or doctor's office setting, and should be used according to the environmental conditions specified below:

  **Ambient Temperature Range:** 0°C to 40°C (32°F to 104°F)
  **Relative Humidity Range:** 5% to 95% (non-condensing)
  **Atmosphere Pressure:** 500 hPa to 1060 hPa

## FCC Compliance Statement

In the United States use of this device is regulated by the Federal Communications Commission (FCC). The device with its antenna complies with FCC's RF exposure limits for general population/uncontrolled exposure.

FCC Warning (Part 15.21): Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the device.

WAM FCC ID: HJR-WAM2500
UTK FCC ID: HJR-UTK2500

These devices comply with Part 15 of the FCC rules. Operation is subject to the following conditions:

1. This device may not cause harmful interference, and

2. This device must accept any interference received, including interference that may cause undesired operation.

## Industry Canada Compliance Statement

These devices comply with RSS-210 of the Industry Canada rules. Operation is subject to the following two conditions:

1. This device may not cause interference, and

2. This device must accept any interference, including interference that may cause undesired operation of the device.

WAM IC: 3758B-WAM2500
UTK IC: 3758B-UTK2500

The term **"IC:"** before the certification/registration number only signifies that the Industry Canada technical specifications were met.

## Note(s)

- Proper patient preparation is important to proper application of ECG electrodes and operation of the device.
- If electrode is not properly connected to the patient, or one or more of the patient cable lead wires is damaged, display will indicate a lead fault for the lead(s) where the condition is present.
- WAM™ (wireless acquisition module) must be paired to electrocardiograph before operation. If you possess more than one WAM, you are advised to label it and the paired electrocardiograph in order to avoid confusion. A sheet of labels is provided with the WAM for convenience.
- For additional instructions and warnings, refer to the user manual of the receiving device.
- As defined by IEC 60601-1 and IEC 60601-2-25, the device is classified as follows:
  - Class I equipment or internally powered.
  - Type CF (ECG) defibrillation-proof applied parts.
  - Equipment not suitable for use in the presence of a flammable anesthetic mixture.
  - Continuous operation.
- The device will automatically start flashing LEDs if the batteries have been discharged below 1.0 volts.
- During normal operation, the green LED will display continuously.
- If the battery cover is opened during transmission, the device will stop transmitting. The battery must be reinserted and the cover must be applied to resume operation.
- The device will automatically turn off (LEDs off) if the battery has been severely discharged.
- The device will automatically turn off when the electrocardiograph is powered down.
- The device will automatically turn off after 15 minutes of being disconnected from the patient. This will happen regardless of the ELI 350, ELI 150c, or ELI 250c battery/AC power state.
- When using the ELI 350, switching to a direct patient cable will automatically power down the device.
- When pairing with the device ensure the AM12 has been disconnected or the pairing operation will fail.
- To perform a STAT ECG using the device paired with an ELI 230 electrocardiograph, user must select STAT at the electrocardiograph to continue.
- A square wave presentation on the display while using the WAM may be due to the WAM being turned off, having no battery, not being paired correctly, operating out of range, or due to a calibration error. Review the LED indicator and auditory advisory on the WAM to ensure the unit is turned on, has proper battery level, is paired correctly, and is within recommended proximity of the electrocardiograph, or power cycle the WAM to re-calibrate. See section 2 “Equipment preparation” for details.
- The device is UL classified:

WITH RESPECT TO ELECTRIC SHOCK,
FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH
UL2601-1, IEC60601-1, CAN/CSA CC22.2 No. 601.1, IEC60601-2-25,

# EQUIPMENT SYMBOLS AND MARKINGS

## Symbol Delineation

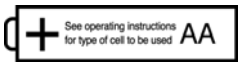
Attention, consult accompanying documents

Defibrillator-proof type CF applied part

Acquire 12 Lead ECG

Acquire Rhythm Print

On / Off button




Battery with notification: See operating instructions for type of cell to be used

Do not dispose as unsorted municipal waste. Per European Union Directive 2002/96, requires separate handling for waste disposal according to national requirements

Indicates compliance to applicable European Union directives

# GENERAL CARE

## Precautions

- Turn off the device before inspecting or cleaning.
- Do not immerse the device in water.
- Do not use organic solvents, ammonia-based solutions, or abrasive cleaning agents which may damage equipment surfaces.

## Inspection

Inspect your equipment daily prior to operation. If you notice anything that requires repair, contact an authorized service person to make the repairs.

- Verify that all cables and connectors are securely seated.
- Check the case for any visible damage.
- Inspect cables and connectors for any visible damage.
- Inspect buttons and controls for proper function and appearance.

## Cleaning and Disinfection

Refer to section 4 for proper cleaning and disinfection procedures.

## Sterilization

Do not sterilize the device or patient cables with Ethylene Oxide (EtO) gas.

## Cautions

Improper cleaning products and processes can damage the device, produce brittle lead wires and cables, corrode the metal, and void the warranty. Use care and proper procedure whenever cleaning or maintaining the device.

# ELECTROMAGNETIC COMPATIBILITY (EMC)

Electromagnetic compatibility with surrounding devices should be assessed when using the device.

An electronic device can either generate or receive electromagnetic interference. Testing for electromagnetic compatibility (EMC) has been performed on the device according to the international standard for EMC for medical devices (IEC 60601-1-2). This IEC standard has been adopted in Europe as the European Norm (EN 60601-1-2).

The device should not be used adjacent to, or stacked on top of other equipment. If the device must be used adjacent to or stacked on top of other equipment, verify that the device operates in an acceptable manner in the configuration in which it will be used.

Fixed, portable, and mobile radio frequency communications equipment can affect the performance of medical equipment. See Table X-4 for recommended separation distances between the radio equipment and the device.

The use of accessories, transducers, and cables other than those specified by Mortara Instrument may result in increased emissions or decreased immunity of the equipment.

## Guidance and Manufacturer's Declaration: Electromagnetic Emissions

The equipment is intended for use in the electromagnetic environment specified in the table below. The customer or the user of the equipment should ensure that it is used in such an environment.

| Emissions Test | Compliance | Electromagnetic Environment: Guidance |
|---|---|---|
| RF Emissions<br>CISPR 11 | Group 2 | The equipment must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected. |
| RF Emissions<br>CISPR 11 | Class B | The equipment is suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| Harmonic Emissions<br>IEC 61000-3-2 | Not Applicable | |
| Voltage Fluctuations/<br>Flicker Emissions<br>IEC 61000-3-3 | Not Applicable | |

## Guidance and Manufacturer's Declaration: Electromagnetic Immunity

The equipment is intended for use in the electromagnetic environment specified in the table below. The customer or the user of the equipment should ensure that it is used in such an environment.

| Emissions Test | Compliance | Compliance Level | Electromagnetic Environment: Guidance |
|---|---|---|---|
| Electrostatic discharge (ESD)<br>IEC 61000-4-2 | +/- 6 kV contact<br>+/- 8 kV air | +/- 6 kV contact<br>+/- 8 kV air | Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. |
| Electrical fast transient/burst<br>IEC 61000-4-4 | +/- 2 kV for power supply lines<br>+/- 1 kV for input/output lines | Not Applicable | |
| Surge<br>IEC 61000-4-5 | +/- 1 kV differential mode<br>+/- 2 kV common mode | Not Applicable | |
| Voltage dips, short interruptions, and voltage variations on power supply input lines<br>IEC 61000-4-11 | <5% UT<br>(>95% dip in UT)<br>for 0.5 cycle<br>40% UT<br>(60% dip in UT)<br>for 5 cycles | Not Applicable | |
| Power frequency (50/60 Hz) magnetic field | 3 A/m | 3 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |

***NOTE:*** *UT is the AC Mains voltage prior to application of the test level.*

## Guidance and Manufacturer's Declaration: Electromagnetic Immunity

The equipment is intended for use in the electromagnetic environment specified in the table below. The customer or the user of the equipment should ensure that it is used in such an environment.

<table>
<tr><th>Emissions Test</th><th>IEC 60601 Test Level</th><th>Compliance Level</th><th>Electromagnetic Environment: Guidance</th></tr>
<tr><td>Conducted RF<br>IEC 61000-4-6</td><td>3 Vrms<br>150 kHz to<br>80 MHz</td><td>3 Vrms<br>150 kHz to<br>80 MHz</td><td rowspan="2">Portable and mobile RF communications equipment should be used no closer to any part of the equipment, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.<br><br>Recommended separation distance<br><br>$d = \left[\frac{3.5}{3Vrms}\right]\sqrt{P}$<br><br>$d = \left[\frac{3.5}{3V/m}\right]\sqrt{P}$ 80 MHz to 800 MHz<br><br>$d = \left[\frac{7}{3V/m}\right]\sqrt{P}$ 800 MHz to 2.5 GHz<br><br>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).<br><br>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b].<br><br>Interference may occur in the vicinity of equipment marked with the following symbol:<br><br> </td></tr>
<tr><td>Radiated RF<br>IEC 61000-4-3</td><td>3 V/m<br>80 MHz to<br>2.5 GHz</td><td>3 V/m<br>80 MHz to<br>2.5 GHz</td></tr>
</table>

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radios, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the equipment is used exceeds the applicable RF compliance level above, the equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the equipment.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [3] V/m.

## Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Equipment

The equipment is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the equipment can help to prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the equipment as recommended in the table below, according to the maximum output power of the communications equipment.

| Rated Maximum Output Power of Transmitter W | Separation Distance According to Frequency of Transmitter (m) | |
|---|---|---|
| | 150 KHz to 800 MHz | 800 MHz to 2.5 GHz |
| | $d = 1.2\sqrt{P}$ | $d = 2.3\sqrt{P}$ |
| 0.01 | 0.1 m | 0.2 m |
| 0.1 | 0.4 m | 0.7 m |
| 1 | 1.2 m | 2.3 m |
| 10 | 4.0 m | 7.0 m |
| 100 | 12.0 m | 23.0 m |

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

***NOTE 1:*** *At 800 MHz, the separation distance for the higher frequency range applies.*

***NOTE 2:*** *These guidelines may not apply in all situations. Electromagnetic propagation is affected by the absorption and reflection from structures, objects, and people.*

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# INTRODUCTION



## Manual Purpose

This manual is intended to provide the user with information about:

- Using and understanding the WAM (wireless acquisition module), the operator buttons, and the LED indicators.
- Preparing the WAM for use. (Section 2)
- Acquiring and printing an ECG. (Section 3)
- Maintenance. (Section 4)

***NOTE:*** *This manual may contain screen shots. Any screen shots are provided for reference only and are not intended to convey actual operating techniques. Consult the actual screen in the host language for specific wording.*

## Audience

This manual is written for clinical professionals who are expected to have a working knowledge of medical procedures and terminology as required for monitoring and/or acquiring clinical data from cardiac patients.

## Indications for Use

- Indicated for use as a radiofrequency physiological signal transmitter that acquires and delivers RF transmission of electrocardiographic data obtained during resting/physiologic electrocardiographic testing.
- Indicated for use in a clinical setting, by qualified medical professionals, properly trained for acquiring ECG data and use of the system. The personnel must be experienced in cardiovascular problematic situations and emergency procedures or pathologies related to cardiac involvements. It is not intended as a sole means of diagnosis.
- Indicated for use in hospital and physicians office, patients of any age where ECG acquisition is done (e.g., patients in Coronary Care Units, Step-Down Units, Emergency Departments, clinics, physicians offices, sports medicine facilities, or rehabilitation departments).
- It is not designed for use in highly invasive environments, such as an operating theatre.

## System Description

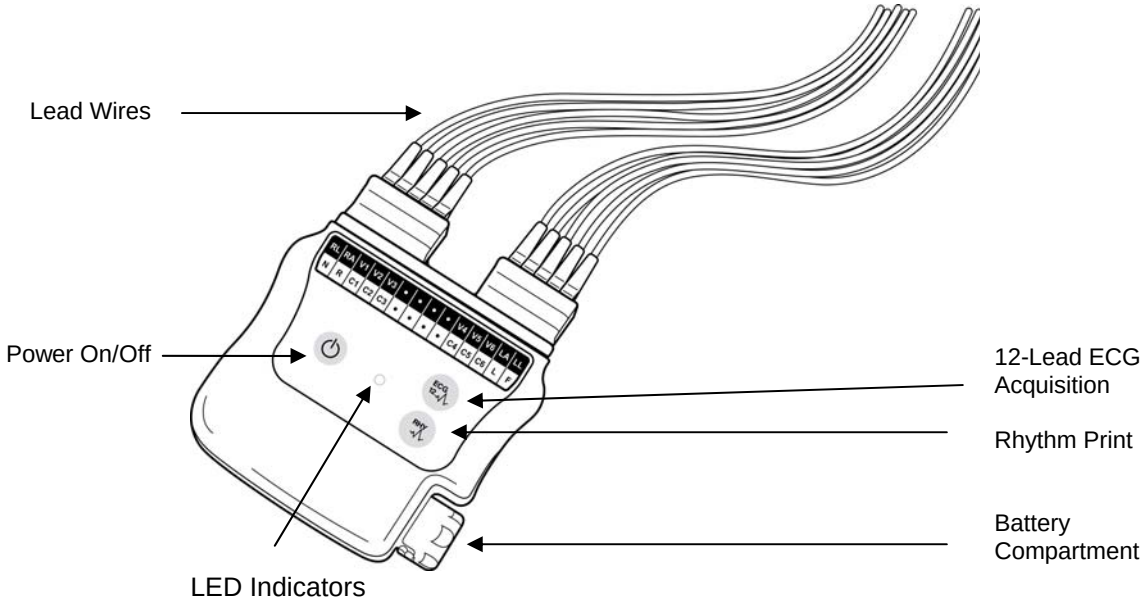
The WAM incorporates wireless electrocardiographic technology to achieve the acquisition and RF transmission of diagnostic-quality 12-lead ECG data. Transmission of the ECG data to a Mortara receiver module allows the cardiac signals to be displayed on a monitoring device, such as an electrocardiograph, without the need for a direct connection.

The following equipment is necessary to use the WAM:

- One AA alkaline battery, 1.5V
- Electrocardiograph with Mortara receiver module
- Lead wire sets
- ECG electrodes

## WAM with Lead Wires

**Figure 1-1**




## Using the Buttons

The WAM is operated by three buttons located on the front of the device:

- Power On/Off
- Acquiring a 12-lead ECG
- Acquiring a rhythm strip

## Approved Battery Models

| Description | Manufacturer | Part Numbers |
|---|---|---|
| Alkaline, AA-type, 1.5V | Various | Various |

***WARNING:*** *Use of other cells may present a risk of fire or explosion.*

To order additional supplies, contact a Mortara Instrument customer service representative.

## Part Numbers

| Description | Part Numbers |
|---|---|
| Wireless Acquisition Module | WAM-XXX-XXXXX |
| WAM ACCESSORY KIT WITH AHA BANANA LEADS | 41000-031-50 |
| WAM ACCESSORY KIT WITH IEC BANANA LEADS | 41000-031-51 |
| WAM ACCESSORY KIT WITH AHA CLIP LEADS | 41000-031-52 |
| WAM ACCESSORY KIT WITH IEC CLIP LEADS | 41000-031-52 |
| BATTERY CAP ASSEMBLY WAM | 8356-008-51 |
| COMBINER WAM LEADS 10 POSITION IEC & AHA GRAY | 9293-046-07 |
| RPLCE LD SET WAM/AM12 FULL SET BANA AHA GRAY | 9293-046-60 |
| RPLCE LD SET WAM/AM12 FULL SET BANA IEC GRAY | 9293-046-61 |
| RPLCE LD SET WAM/AM12 LIMBS BANA AHA GRY | 9293-046-62 |
| RPLCE LD SET WAM/AM12 LIMBS BANA IEC GRY | 9293-046-63 |
| RPLCE LD SET WAM/AM12 V1-V3 BANA AHA GRY | 9293-046-64 |
| RPLCE LD SET WAM/AM12 C1-C3 BANA IEC GRY | 9293-046-65 |
| RPLCE LD SET WAM/AM12 V4-V6 BANA AHA GRY | 9293-046-66 |
| RPLCE LD SET WAM/AM12 C4-C6 BANA IEC GRY | 9293-046-67 |
| RPLCE LD SET WAM/AM12 FULL SET CLIP AHA GRAY | 9293-047-60 |
| RPLCE LD SET WAM/AM12 FULL SET CLIP IEC GRAY | 9293-047-61 |
| RPLCE LD SET WAM/AM12 LIMBS CLIP AHA GRY | 9293-047-62 |
| RPLCE LD SET WAM/AM12 LIMBS CLIP IEC GRY | 9293-047-63 |
| RPLCE LD SET WAM/AM12 V1-V3 CLIP AHA GRY | 9293-047-64 |
| RPLCE LD SET WAM/AM12 C1-C3 CLIP IEC GRY | 9293-047-65 |
| RPLCE LD SET WAM/AM12 V4-V6 CLIP AHA GRY | 9293-047-66 |
| RPLCE LD SET WAM/AM12 C4-C6 CLIP IEC GRY | 9293-047-67 |
| LEAD SET WAM/AM12 10-WIRE SHORT CLIPS AHA GRAY | 9293-047-70 |
| LEAD SET WAM/AM12 10-WIRE SHORT CLIPS IEC GRAY | 9293-047-71 |
| RPLCE LEAD SET WAM/AM12 LIMBS SHORT CLIPS AHA GRAY | 9293-047-72 |
| RPLCE LEAD SET WAM/AM12 LIMBS SHORT CLIPS IEC GRAY | 9293-047-73 |
| RPLCE LEAD SET WAM/AM12 V1-V3 SHORT CLIPS AHA GRAY | 9293-047-74 |
| RPLCE LEAD SET WAM/AM12 C1-C3 SHORT CLIPS IEC GRAY | 9293-047-75 |
| RPLCE LEAD SET WAM/AM12 V4-V6 SHORT CLIPS AHA GRAY | 9293-047-76 |
| RPLCE LEAD SET WAM/AM12 C4-C6 SHORT CLIPS IEC GRAY | 9293-047-77 |
| WAM USER MANUAL CD | 9515-174-50-CD |

## Specifications

| Feature | Specification* |
|---|---|
| Instrument Type | 12-lead wireless acquisition module for resting ECG |
| Input Channels | 12-lead signal acquisition and transmission |
| ECG Leads Transmitted | I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, and V6 |
| WAM Transmission Protocol | Bidirectional and frequency hopping; beacon and response method links a single acquisition module to a single electrocardiograph |
| Frequency Range | 2400.96 MHz to 2482.56 MHz |
| WAM and Receiver Distance | Approximately 10 feet (3 meters) |
| Lead Set | RA, LA, RL, LL, V1, V2, V3, V4, V5, and V6 (R, L, N, F, C1, C2, C3, C4, C5, and C6) with detachable lead wires |
| Sampling Rate | 40,000 samples/second/channel acquisition; 1,000 samples/second/channel transmitted for analysis |
| Resolution | 1.875 microvolt LSB |
| User Interface | Three-button operation: ON/OFF, 12-lead ECG acquisition, and rhythm strip acquisition |
| Defibrillator Protection | Complies with AAMI standards and IEC 60601-2-25 |
| Special Functions | LED indication of power status, operating mode, lead fail, and remaining battery charge |
| Device Classification | Type CF, battery operated |
| Weight | 6.7 oz. (190 g) with battery |
| Dimensions | 4.45 x 4.25 x 1.1” (11.3 x 10.8 x 2.79 cm) |
| Battery | 1 AA alkaline battery typically powers WAM for acquisition of 250 resting ECGs |

**Specifications subject to change without notice.*

# EQUIPMENT PREPARATION



## Battery Installation

The WAM is powered with a single AA battery. When the battery contains sufficient voltage to operate and the patient is properly connected, an LED on the front of the WAM will appear solid green indicating proper pairing and communication with the electrocardiograph. A battery with low voltage or a lead fail will result in a flashing green or yellow LED.

To install a new battery, remove the battery cover by twisting the cover in a counterclockwise direction. Removal of the battery cover will automatically turn the power off. Insert one AA battery into the battery compartment aligning the battery's positive (+) and negative (-) indicators with the designators shown on the device's back label. Replace the battery cover by twisting the cover in a clockwise direction. The battery cover will seal the battery compartment and make contact with the battery providing power to the device.

## Applying Power

Before you apply power to the WAM, make sure that patient lead wires do not touch metal connected to ground (this may happen if reusable electrodes with exposed metal are used); the WAM will auto-calibrate at power-on, and a large amount of noise caused by ground loops may disrupt calibration, in which case the electrocardiograph will not display the ECG.

Press the power On/Off button. On initial start up, the LEDs will briefly flash yellow and green and the device will beep. LED status will indicate the following:

- Solid green: appropriate battery power level, good electrode-to-skin impedance, and good bidirectional communication with the electrocardiograph.
- Flashing green: low battery.
- Solid yellow: lead fail.
- Flashing yellow: low battery and/or lead fail.
- LED off: device not powered on, very low battery (no sound), or device out of range (WAM will beep intermittently).

Press the power On/Off button to turn the device off. An audible tone will sound indicating power off and RF disconnect.

## Attaching the Lead Wire Connector Block

The 12-lead ECG lead wires consist of one connector block with 10 lead wires (5 leads wires to each side). The lead wires are positioned on the WAM to follow the contour of the torso. Each lead wire terminates in a medi-clip or 4 mm banana connector.

Securely insert the connector block into the ECG input connector on the top of the WAM.

***CAUTION:*** *Be careful to insert the connector block into the appropriate input connector by matching the lead wire labels to the WAM label.*

## Labeling the WAM and Electrocardiograph

The WAM ships with self-adhesive letters allowing the user to label the WAM and its paired electrocardiograph. It is recommended these labels are applied to both the WAM and its paired electrocardiograph to assist in keeping the units together.

## Pairing with an ELI 150c/ELI 250c

Power on the ELI 150c or ELI 250c and:

- Select **F6 MORE**.
- Select **F6 MORE**.
- Select **F2 WAM Pairing**.
- Place the WAM (powered off) on top of the electrocardiograph.
- Select **START,** then turn WAM on**.**
- Enter password.
- A successfully paired message will display.
- Follow instructions on the display.

***NOTE**: When pairing with the WAM ensure the AM12 has been disconnected or the pairing operation will fail.*

***NOTE**: The WAM will automatically turn off when the electrocardiograph is powered down.*

***NOTE**: The WAM will automatically turn off after 15 minutes of being disconnected from the patient. This will happen regardless of the ELI 150c or ELI 250c battery/AC power state.*

## Pairing with an ELI 230

Power on the ELI 230 and:

- Select **MORE**.
- Select **CONFIG**.
- Select **4 Service**.
- Select **Yes**.
- Select **2 WAM Pairing**.
- Place the WAM (powered off) on top of the ELI 230.
- Select **START,** then turn WAM on**.**
- A successfully paired message will display.
- Select **DONE**.
- Restart the ELI 230.

## Pairing with an ELI 280

Power on the ELI 280 and:

- Select **SETTINGS**.
- Select **WAM**.
- Place the WAM (powered off) on top of the ELI 280.
- Select **Pairing**.
- Select **START,** then turn WAM on**.**
- A successfully paired message will display.
- Select **DONE**.

## Pairing with an ELI 350

The WAM will not take a 15-lead ECG. If the ELI 350 ECG Acquisition is set at 15 lead, the electrocardiograph will automatically switch to direct patient cable. To take a 12-lead ECG with the WAM the user must select 12 lead in the electrocardiograph's ECG Acquisition menu.

1. Power on the ELI 350 and:

   - Select **Settings** from the main display.
   - Enter password and select **WAM**.
   - Patient cable selection defaults to WAM. Remaining fields will automatically fill when pairing is done.
   - Select **Set Device ID**.
   - Select **Yes** to continue with pairing.
   - Per display instructions, turn off the WAM, place the WAM on top of the ELI 350, and turn the WAM on.
   - A successfully paired message will display.

   **WARNING**: *The ELI 350 does not automatically switch between the WAM and a direct patient cable. Clinician must choose the desired cable in the Settings menu before ECG acquisition. Switching between a direct patient cable and the WAM does not require the WAM to be re-paired with the ELI 350 unless a different WAM is to be used. The selected patient cable will display continuously under the Settings menu button.*

2. When the WAM is paired with an ELI 350 but the WAM is not on or its batteries are depleted, the ELI 350 will flash a "Searching for WAM" message under the Settings menu button.

3. When the WAM is on and within range, the ELI 350 will display "WAM" and up to five signal bars. Also displayed is a battery gauge: green signifies adequate battery strength; red means the battery needs to be replaced immediately.

4. When the WAM is on and within range but is not connected to a patient, "Leads Off" will display on the ELI 350 underneath heart rate. ECG leads will display as square waves.

   ***NOTE**: When using the ELI 350, switching to a direct patient cable will automatically power down the WAM.*

   ***NOTE**: The WAM will automatically turn off when the electrocardiograph is powered down.*

   ***NOTE**: The WAM will automatically turn off after 15 minutes of being disconnected from the patient. This will happen regardless of the ELI 350 battery/AC power state.*

## Lead Fail

Lead fail is done automatically through visual communication with the LEDs located on the front of the WAM. A yellow LED (solid or flashing) indicates a lead fail condition is present. A solid green LED indicates proper lead connection as well as adequate battery voltage for ECG acquisition.

## LED Indicators

| LED | + Audio | MODE |
|---|---|---|
| GREEN off<br>YELLOW off | Intermittent beeping | Device is on but not paired to an electrocardiograph, is out of range of the paired electrocardiograph, or when used with ELI 350 could signify that direct patient cable is selected. |
| YELLOW solid or flashing<br>GREEN off | | One or more leads are not connected properly. |
| GREEN solid<br>YELLOW off | | No lead fail condition is detected; battery is OK. |
| GREEN solid<br>YELLOW off | Intermittent beeping | Device is collecting a 10-second ECG. |
| Blinking LED<br>(yellow or green depending on lead fault status) | | Device has detected a low battery condition. Replace the battery within 15 minutes. |
| GREEN off<br>YELLOW off | 1 second audio on, then device turns off. | Device has detected a very low battery status and powered off. |

# ACQUIRING AN ECG



Use the LED indicators to check electrode-to skin impedance and verify patient hookup quality, as well as to ensure communication has been established with the electrocardiograph and the signal quality of each ECG is transmitted as expected. A yellow LED indicates a lead fail condition.

1. Ensure an AA battery is in the battery compartment. If battery voltage is too low, the WAM may not power on. Insert a new AA battery into the device to continue operation.

2. Press the On/Off button to turn the WAM on.

3. Connect the patient to the WAM lead wires (see *Patient Hookup in the recording device user manual*).

4. ECG data should be automatically transmitted to the recording device.

5. Enter patient information at the recording device.

6. Press the 12-Lead ECG Acquisition button to complete the acquisition of the 12-lead ECG.

7. Press the Rhythm Print button to acquire a rhythm print; press the Rhythm Print button again to stop the rhythm print.

   ***NOTE**: During normal operation, the green LED will display continuously.*

   ***NOTE**: If the battery cover is opened during transmission, the WAM will stop transmitting. The battery must be reinserted and the cover must be applied to resume operation.*

   ***NOTE**: Using the buttons to acquire a 12-lead ECG or a rhythm strip is not functional with XScribe.*

8. At the end of the ECG acquisition session, the WAM should be turned off. ECG data may now be reviewed, plotted, or edited as needed at the electrocardiograph

   ***NOTE**: To perform a STAT ECG using the WAM paired with an ELI 230 electrocardiograph, user must select STAT at the electrocardiograph to continue.*

# MAINTENANCE



## Cleaning the WAM and ECG Lead Wires

1. Remove all lead wires and the power source from the WAM before cleaning.
2. For general cleaning, use a soft, lint-free cloth lightly moistened with a mild soap and water solution. Wipe and air dry.
3. For disinfecting, wipe exterior with a soft, lint-free cloth using a solution of Sodium Hypochlorite (10% household bleach and water solution) minimum 1:500 dilution (minimum 100 ppm free chlorine) and maximum 1:10 dilution as recommended by the APIC Guidelines for Selection and Use of Disinfectants.
4. Use caution with excess liquid as contact with metal parts may cause corrosion.
5. Do not immerse lead wires; immersion can cause metal corrosion.
6. Do not use excessive drying techniques such as forced heat.

***WARNING****: Prevent liquid from penetrating the device and do not attempt to clean/disinfect the device or lead wires by submerging into a liquid, autoclaving, or steam cleaning. Never expose lead wires to strong ultra-violet radiation. Do not sterilize the device or patient cables with Ethylene Oxide (EtO) gas.*

## Periodic Maintenance

Check the WAM and lead wires before each use to ensure they are not damaged or broken.

## Disposal of Waste Materials

The WAM uses one AA battery and disposable ECG electrodes. Disposal must be in accordance with the following procedures:

Battery: applicable disposal or recycling standards

Electrodes: normal waste

# MESSAGES AND INFORMATION

APPENDIX A

The following table defines LED signals seen at the WAM during patient hookup and transmission.

| Message | Solution |
|---|---|
| LED off, intermittent beeping | WAM is on but not synched to an electrocardiograph. Ensure that the electrocardiograph is turned on. Follow the pairing process if necessary. |
| Solid green LED | No interaction required. |
| Flashing green LED | Replace AA battery. |
| Solid yellow LED | Lead fail message, check leads for proper connection. |
| Flashing yellow LED | Low battery and lead fail condition exist. Replace battery and check leads for proper connection. |
| LED Off, no beeping | Power is off, press power button to turn on. If no audible beeping is heard, battery is completely depleted. Replace battery to power on the WAM. If beeping is heard ensure you are within 10 ft. (3 meters) of the paired electrocardiograph. |

The following messages are seen on the ELI electrocardiograph where applicable. NOTE: lead wire messages will be seen on the ELI electrocardiograph display and not on the WAM; the WAM will display a yellow LED in the event of a lead failure.

| Message | Solution |
|---|---|
| RA or N | RA or N fail. Check if the lead wire is off or the electrode needs to be replaced. |
| RL or R | RL or R fail. Check if the lead wire is off or the electrode needs to be replaced. |
| LA or F | LA or F fail. Check if the lead wire is off or the electrode needs to be replaced. |
| LL or L | LL or L fail. Check if the lead wire is off or the electrode needs to be replaced. |
| A combination of RA/…/LL or N…F | More than one limb lead fail or all leads fail. Check the lead wires and electrodes. |
| V1 or C1 | V/C1 fail. Check if the lead wire is off or the electrode needs to be replaced. |
| V2 or C2 | V/C2 fail. Check if the lead wire is off or the electrode needs to be replaced. |
| V3 or C3 | V/C3 fail. Check if the lead wire is off or the electrode needs to be replaced. |
| V4 or C4 | V/C4 fail. Check if the lead wire is off or the electrode needs to be replaced. |
| V5 or C5 | V/C5 fail. Check if the lead wire is off or the electrode needs to be replaced. |
| V6 or C6 | V/C6 fail. Check if the lead wire is off or the electrode needs to be replaced. |
| A combination of V1, V2, V3, V4, V5, V6, or C1, C2, C3, C4, C5, C6 | More than one chest lead fails. Check the lead wires and electrodes. |

The following system information log is provided for your convenience. You need this information if your device needs servicing. Be sure to update the information log when you add options or your device has been serviced.

Record the model and serial number of all components, dates of removal and/or replacement, and the name of the vendor from whom the component was purchased and/or installed.

In addition to having records of this information, the system information log provides a warranty record of when your device was placed in service.

## System Information Log

Manufacturer:

Mortara Instrument, Inc.
7865 N. 86th St.
Milwaukee, WI 53224

Telephone Numbers:

USA: 800-231-7437
European: +39-51-6650-701

Sales Department: 800-231-7437
Service Department: 888-MORTARA

**Product Information:**

Name of Unit/Product: _____

Date of Purchase: ___/___/_____

Purchased Unit From: _____

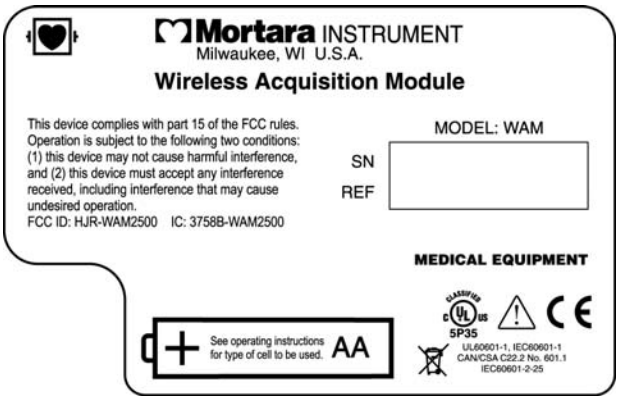
Serial Number: _____

Software Version: _____

## Serial and Part Number Location

For questions and service information, have both serial and part number available when calling.

The model type, serial number (SN), and part number (REF) are found on the back label of the device similar to the one pictured below.


Mortara INSTRUMENT
Milwaukee, WI U.S.A.
Wireless Acquisition Module
This device complies with part 15 of the FCC rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.
FCC ID: HJR-WAM2500 IC: 3758B-WAM2500
MODEL: WAM
SN
REF
MEDICAL EQUIPMENT
See operating instructions for type of cell to be used.
AA
5P35
UL60601-1, IEC60601-1
CAN/CSA C22.2 No. 601.1
IEC60601-2-25